

REMARKS

This Reply is responsive to the Office Action dated October 21, 2004. Entry of the amendments and remarks submitted herein and reconsideration of the claimed subject matter pursuant to 37 CFR §1.116 is respectfully requested.

I. Status of the Claims

Claims 1-14 were pending in this application at the time of the Office Action dated June 3, 2003. Claims 8 and 10-13 were withdrawn from consideration. Claim 14 has been canceled by way of amendment above. Accordingly, claims 1-7 and 9 are now under examination.

II. Amendments to the Claims

Claim 1 has been amended above to emphasize that according to the claimed method, the heavy chain antibodies are produced in a cellular compartment of a plant by introducing into the plant a DNA sequence encoding the heavy chain antibody, which also includes a sequence expressing a peptide which targets the antibody to the selected cellular compartment. Support for this amendment to claim 1 is found in claim 14. Accordingly, claim 14 has been canceled.

Claim 1 has also been amended to clarify that the antibodies produced by the claimed method are functional, and that the antibodies are heavy chain only antibodies in the sense that antigen binding capacity is located in a single binding domain and does not require a variable light chain domain. Support for these amendments may be found at the very least at page 8, lines 25-26, and page 17, lines 7-13.

No prohibited new matter has been added by way of these amendments.

III. Rejections under §112, Second Paragraph and §101

Claim 1 and claims 2-7 and 9 were rejected under 35 U.S.C. §112, second paragraph for alleged indefiniteness. According to the Office Action, claim 1 is indefinite where it merely recites a use without any active positive steps. A corresponding rejection has been set forth under 35 U.S.C. §101.

Without agreeing with the rejection, Applicants note that claim 1 has been amended above to incorporate the limitations of claim 14, thereby providing the method of claim 1 with a positive process step. Accordingly, the rejections under 35 U.S.C. §112, second paragraph and §101 may now be withdrawn.

IV. Prior Art Rejections

Claims 1, 3, 7, 9 and 14 remain rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Magnuson *et al.* According to the Office Action, the rejection remains because the claims recite no method steps that require the growth of a multicellular plant such that the claims can be distinguished from the method taught by Magnuson, which teaches the production of antibodies in cell suspension. Without agreeing with the rejection and solely in an effort to expedite allowance, Applicants note that claim 1 has been amended above to clarify that the antibodies of the present invention are produced in a selected cellular compartment in a plant. Reconsideration and withdrawal of the rejection under §102(b) based on Magnuson *et al.* are respectfully requested.

Claims 1, 2, 7, 9 and 14 remain rejected under 35 U.S.C. §102(b) as being allegedly anticipated by Casterman *et al.* According to the Office Action, the rejection is maintained because claims 1, 2, 7 and 9 recite no method steps, and because the claims do not require the production of heavy chain only immunoglobulins that are functional in absence of light chain (Office Action, page 6 and paragraph bridging pages 8-9).

Without agreeing with the rejection and solely in an effort to expedite allowance, Applicants note that claim 1 has been amended to include the positive process steps of introducing and expressing a DNA sequence encoding the heavy chain antibody in addition to a peptide sequence that targets the antibody to a selected cellular compartment.

With regard to the Examiner's assertion that the heavy chain antibodies referred to in the claims need not be functional, Applicants respectfully disagree. Applicants believe that claim 1 has always made it clear that the antibody or active fragment thereof shows antigen binding activity. Nevertheless, solely to expedite allowance of the present invention, claim 1 has been amended above to clarify that the claimed method produces functional heavy chain antibodies.

With regard to the assertion that the claims do not require the production of heavy chain "only" immunoglobulins, Applicants respectfully disagree. Applicants believe that the statement in claim 1 that the heavy chain antibody is devoid of a variable light chain domain makes it clear that the antibodies are heavy chain only antibodies and not merely heavy chain only antibodies at the point of production. Applicants believe that this would be quite clear when the claim is read in the context of the specification, which states on page 8, lines 26-29, that isolated VH domains of conventional antibodies are not

included within the scope of the invention. Nevertheless, solely in an effort to expedite allowance of the present invention, claim 1 has been amended above to clarify that the antigen binding capacity of the heavy chain antibodies produced by the present invention resides in a single binding domain.

As the above amendments appear to resolve the reasons provided by the Examiner for maintaining the rejection over Applicants' previous arguments, Applicants respectfully request entry if the amendments to claim 1 and reconsideration and withdrawal of the rejection under §102(b) based on *Casterman et al.*

Claim 4 remains rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over either *Magnuson et al.* or *Casterman et al.* in view of *Owen et al.* According to the Office Action, the rejection remains because the claims recite no method steps directed to the production of antibodies in compartments of a real plant. Without agreeing with the rejection and solely in an effort to expedite allowance, Applicants note that claim 4 is dependent on claim 1, which has been amended above to clarify that the antibodies of the present invention are produced in a selected cellular compartment in a plant. Reconsideration and withdrawal of the rejection under §103(a) based on *Magnuson et al.* or *Casterman et al.* in view of *Owen et al.* are respectfully requested.

Claim 5 remains rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over either *Magnuson et al.* or *Casterman et al.* in view of *Le Gall et al.* According to the Office Action, the rejection remains because the claims recite no method steps directed to the production of antibodies in compartments of a real plant. Without agreeing with the rejection and solely in an effort to expedite allowance,

Applicants note that claim 5 is dependent on claim 1, which has been amended above to clarify that the antibodies of the present invention are produced in a selected cellular compartment in a plant. Reconsideration and withdrawal of the rejection under §103(a) based on Magnuson *et al.* or Casterman *et al.* in view of Le Gall *et al.* are respectfully requested.

Claim 6 was rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over either Magnuson *et al.* or Casterman *et al.* in view of Artsaenko *et al.* According to the Office Action, the rejection remains because the claims recite no method steps directed to the production of antibodies in compartments of a real plant. Without agreeing with the rejection and solely in an effort to expedite allowance, Applicants note that claim 6 is dependent on claim 1, which has been amended above to clarify that the antibodies of the present invention are produced in a selected cellular compartment in a plant. Reconsideration and withdrawal of the rejection under §103(a) based on Magnuson *et al.* or Casterman *et al.* in view of Artsaenko *et al.* are respectfully requested.

This reply is fully responsive to the Office Action dated October 21, 2004.

Accordingly, Applicants respectfully urge that entry of all amendments and indication of allowable subject matter is now appropriate.

Except for issue fees payable under 37 CFR §1.18, the commissioner is hereby authorized by this paper to charge any additional fees during the pendency of this application including fees due under 37 CFR §1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-0310. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 CFR §1.136(a)(3).

If the Examiner has any further questions relating to this Reply or to the application in general, she is respectfully requested to contact the undersigned by telephone so that allowance of the present application may be expedited.

Respectfully submitted
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